

Application Number 10/767,545  
Responsive to Office Action mailed February 2, 2007

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**REMARKS**

This submission is responsive to the Office Action dated February 2, 2007. Claims 1-54 are pending, with claims 1-18 withdrawn due to restriction.

**Claim Rejection Under 35 U.S.C. § 102(b)**

The Office Action rejected claims 19-29, 32-47 and 50-54 under 35 U.S.C. § 102(b) as being anticipated by Kroll et al. (US 7,123,961, herein referred to as Kroll). Applicant respectfully traverses the rejection. Kroll fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

***Independent claims 19 and 37***

Kroll fails to teach or suggest a computer-readable medium comprising instructions to cause a processor to select a first parameter configuration for a neurostimulator, receive an indication of observed efficacy of the first parameter configuration, and select a second parameter configuration for the neurostimulator based on the indication of observed efficacy and a set of additional electrode configurations identified by a decision tree, as recited by Applicant's independent claim 19.

Similarly, with respect to independent claim 37, Kroll fails to disclose or suggest a device comprising a processor programmed to select a first parameter configuration for a neurostimulator, receive an indication of observed efficacy of the first parameter configuration, and select a second parameter configuration for the neurostimulator based on the indication of observed efficacy and a set of additional electrode configurations identified by a decision tree.

For example, Kroll does not disclose or suggest selection of a second parameter configuration based on the observed efficacy of a first parameter configuration. Kroll also fails to disclose or suggest the use of a decision tree to identify parameter configurations for a neurostimulator.

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Instead, Kroll describes a device and/or user that positions and/or selects a lead and/or an electrode to deliver a pulse.<sup>1</sup> After the pulse is delivered, a user and/or device determines whether an optimal result was obtained.<sup>2</sup> If the result is not optimal, a device and/or user positions and/or selects a lead and/or an electrode to deliver the next pulse.<sup>3</sup> Multiple positioning and/or selection iterations may be performed until an optimal and/or satisfactory result is produced.<sup>4</sup>

Kroll does not disclose or suggest that the next position or electrode to be tested is determined based on the observed efficacy. Instead, Kroll merely teaches that the decision to continue testing new positions/electrodes is in response to a determination that the response was not optimal. In other words, even if Kroll could be considered to teach why and when a next position/electrode is selected, Kroll does not provide teach how the next position/electrode is selected. Such selection may be random or idiosyncratic. Consequently, Kroll not teach or suggest selecting a second parameter configuration for neurostimulation based on observed efficacy for a first parameter configuration for neurostimulation.

Furthermore, Kroll does not disclose or suggest the use of a decision tree to provide guidance in selecting an electrode configuration. Kroll does not even mention a decision tree. As described in the Summary of Applicant's disclosure, a decision tree may suggest the configurations that are most likely to be efficacious given the results of determinations along the path of the decision tree based on efficacy observations performed during an evaluation session. Kroll does not describe how the position and/or selection of the lead and/or electrode is modified with each iteration and does not disclose or suggest a decision tree to aid in the positioning or selection. For at least these reasons, Kroll fails to disclose or suggest the requirements of independent claims 19 and 37.

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<sup>1</sup> Kroll, column 23, lines 1-2.

<sup>2</sup> Kroll, column 23, lines 13-14.

<sup>3</sup> Kroll, column 23, lines 15-17.

<sup>4</sup> Kroll, column 23, lines 15-20.

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***Claims 20-29, 32-36, 38-47, and 50-54***

Kroll fails to disclose or suggest each and every element set forth in independent claims 19 and 37. Claims 20-29 and 32-36 are dependent upon independent claim 19, and claims 39-47 and 50-54 are dependent upon independent claim 37. For at least the reasons described previously with respect to independent claims 19 and 37, Kroll fails to disclose or suggest the requirements of dependent claims 20-29, 32-36, 38-47, and 50-54.

Additionally, Applicant disagrees with the Office Action's finding that Applicant's claims contain intended use limitations. The Office Action stated, "Applicant's limitations of intended use such as lead placement and suggesting a configuration to the user are given no patentable weight since the leads and communication devices are not specified as part of the invention."<sup>5</sup> Applicant submits that, "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used."<sup>6</sup> Applicant submits that the claims clearly define the invention and requests consideration of all elements of Applicant's claims.

For example, Kroll fails to disclose or suggest a processor that selects first and second parameter configurations by suggesting the first and second parameter configurations to a user, as required by claims 32 and 50, or a processor that receives an indication relating to observed efficacy by receiving user input indicating observed efficacy, as required by claims 33 and 51. Claims 32, 33, 50, and 51 further limit the independent claims by defining functional limitations of the processor. Applicant requests consideration of these claim limitations in the subsequent Office Action.

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<sup>5</sup> Office Action dated 2/2/07, page 2.

<sup>6</sup> MPEP 2173.05(g)

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Further, with respect to claims 23 and 41, Kroll fails to disclose or suggest leads implanted proximate to a spine of a patient. Kroll also fails to disclose or suggest a final electrode configuration that includes electrodes deployed on one more implanted spinal leads, as required by claims 28 and 46. Instead, Kroll describes positioning a lead in and/or near a patient's heart or near an autonomic nerve within a patient's body to affect cardiac function.<sup>7</sup> Additionally, Kroll fails to disclose or suggest updating a decision tree based on observed efficacy, as required by claims 35 and 52. Kroll provides no teaching of decision trees, and certainly does not suggest updating a decision tree.

Further, with respect to claims 37 and 54, Kroll provides no teaching remotely suggestive of applying a first decision tree to determine a neurostimulation therapy type, neurostimulation device type, lead type and symptomatic indication, and applying a second decision tree based on the determination to select the second parameter configuration. The Office Action pointed to FIG. 8 as determining the type of stimulation. Such a teaching would fall well short of what is recited in claims 37 and 54. These claims require determining a neurostimulation therapy type, neurostimulation device type, lead type and symptomatic indication. Moreover, the result of the method of FIG. 8 of Kroll is not application of a second decision tree based on a determination made by the method of FIG. 8.

Kroll fails to disclose each and every limitation set forth in claims 19-29, 32-47, and 50-54. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 19-29, 32-47, and 50-54 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

#### **Claim Rejection Under 35 U.S.C. § 103(a)**

In the Office Action, the Examiner rejected claims 30, 31, 48, and 49 under 35 U.S.C. § 103(a) as being unpatentable over Kroll. Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims.

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<sup>7</sup> Kroll, abstract and column 2, lines 47-62.

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Applicant submits that Kroll fails to disclose or suggest the requirements of claims 30, 31, 48, and 49 for at least the reasons stated previously with respect to independent claims 19 and 37. Claims 30 and 31 are dependent upon claim 19, and claims 48 and 49 are dependent upon claim 37. Dependent claims 30, 31, 48, and 49 are in condition for allowance for at least the reasons stated previously with respect to independent claims 19 and 37.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 30, 31, 48, and 49 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

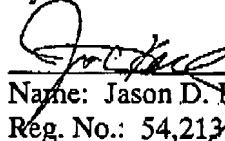
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

5-2-07

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